IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS US LLC; ASTELLAS PHARMA US, INC.; and GILEAD SCIENCES, INC., Plaintiffs, v. APOTEX INC., et al., Defendants.	C.A. No. 18-1675-CFC-CJB (CONSOLIDATED) [redacted] REDACTED

PLAINTIFFS' OBJECTIONS TO MEMORANDUM ORDER [D.I. 874]

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I. INTRODUCTION

The Patents-in-suit claim regadenoson monohydrate, the crystalline form of the active pharmaceutical ingredient (API) in Lexiscan®. Defendants, generic drug companies hoping to sell generic versions of Lexiscan®, and their API suppliers, developed products that [redacted]. After Plaintiffs served final contentions and infringement reports, Defendants—having seen all of Plaintiffs' case—asked the Court to postpone the trial more than 6 months so they and their API suppliers could change their product specifications and ANDAs to bolster Defendants' non-infringement defenses. Because the ANDAs had changed, the Court allowed supplemental discovery. During that discovery period, Plaintiffs produced more evidence of infringement. Judge Burke struck it.

Judge Burke's decision to strike that evidence is clear error. The Third Circuit encourages resolution of disputes on the merits. This is a bench trial, Plaintiffs have produced additional evidence of infringement confirming that [redacted] still occurs despite the change to the ANDA. Rather than allow this Court to weigh the merits of that evidence, Judge Burke found that the evidence—generated in response to Defendants' last-minute amendments—should have been produced before that amendment. That is error—there is no violation of the scheduling order as the evidence was produced during the Court-authorized

supplemental discovery period. Even had there been a violation, Judge Burke erred in applying the *Pennypack* factors, in particular where he found that Defendants were prejudiced by not having an opportunity to test—testing that each of their experts said was either unnecessary or that they had not been asked to consider. The Court should sustain the objection.

II. NATURE AND STAGE OF THE PROCEEDINGS

The trial in this case was delayed because the Defendants, after the original discovery period, changed their ANDAs. The Court held a hearing on the proposed change in April 2021. At that hearing, in response to an argument that the Defendants were innocent bystanders in all of this, the Court asked about the relationship between Defendants and their API suppliers[1]:

> *THE COURT: . . . . And then you got on the phone when I asked to speak to plaintiffs' counsel and you said, hey, just for the record here, as I understood your comment, we didn't really do anything. We're subject to Euticals [an API supplier]. And I'm having a hard time understanding that. I assume you have a contract with Euticals. You're working in concert with Euticals and that's what I'm looking at. So if you are trying to portray your client as kind of this innocent bystander that, you know, that's in the same position as Sun, I'm not seeing it. Now, you should feel -- go ahead. You can educate me and explain how you really are innocent and, you know, poor you is just subject to whatever Euticals does, but I don't see it that way as a kind of outsider.*

D.I. 730-1 at 40:1-15.

[1] API suppliers have to submit their API's specification to FDA in the form of a Drug Master File ("DMF").

After much back and forth, Defendants assured the Court they were separate from their API suppliers, and, therefore, this last-minute change should not be blamed on them.

> *[COUNSEL:] . . . .That Drug Master File is submitted to FDA and none of the Form G defendants, DRL, IMS and Hospira, none of us have control over what they put in that DMF or how they conduct their process or the product they sell. We simply purchase the product that is specified in their DMF.*
>
> *So they are truly separate entities. There is no control between customers, and there are three customers on the line here, DRL, IMS and Hospira and Euticals. Euticals is independent. They can sell to anyone they want. They can change their process any way they see fit and that's the end of it. They are truly independent.*

D.I. 730-1 42:6-16.

The privilege logs tell a different tale. From when Defendants received Plaintiffs' infringement reports to that April 7 conference with the Court, there were [redacted]. *See* Ex. 1 (Curia Privilege Log) at 1-3; Ex. 2 (Biophore Privilege Log) at 1-2.[2,3] And Apotex admitted that [redacted]. *See* Ex. 11 at 310:1-13. Ultimately, the Court set a January 2022 trial date to allow discovery into Defendants' updated ANDAs.

[2] The DMF holders are Biophore (for Apotex) and Euticals, who later changed its name to Curia (for IMS, DRL, and Hospira).

[3] Because the timing of all of this is critically important to understanding what happened, attached as Ex. 3 is a timeline that sets forth the key events.

Plaintiffs' infringement theory has always been that [redacted] *See, e.g.,* Exs. 4 (Apotex Contentions) at 7, 5 (DRL Contentions) at 8-9; 6 (Hospira Contentions) at 5-6; 7 (IMS Contentions) at 6. Originally, Plaintiffs focused on [redacted]. After waiting until Plaintiffs committed to this set of proofs, which Judge Burke coined the "old theory," the Defendants and their API suppliers rolled out amendments to their ANDAs and DMFs to undercut this proof. Ex. 8 at 22:2-23:1.

Plaintiffs' post-ANDA amendment theory did not change. During supplemental discovery, Plaintiffs ***also*** showed that [redacted]. (Judge Burke coined this the "new theory"). Plaintiffs showed this based on tests conducted on the newly-produced product samples. Plaintiffs included this set of proofs in the contentions and supplemental expert reports served in accordance with the Supplemental Scheduling Order. The contentions were served on October 1, 2021 as to DRL, IMS, and Hospira and October 8, 2021 as to Apotex; the supplemental expert reports were served on November 26, 2021. D.I. 817; 820; Ex. 9 at 1-4, Ex. 10 at 1-2.

In response, Defendants' experts, who had the opportunity and time[4] to conduct testing of their own, were never asked to test, or chose not to. *See* D.I. 870-7 (Steed Tr.) at 74:10-16 ([redacted]), D.I. 870-6 (Cockcroft Tr.) at 121:3-12 ([redacted]). Apotex's expert, Dr. Buckton, said [redacted]

[redacted]

D.I. 870-5 at 71:17-72:2 (emphasis added). At the motion to strike hearing, Apotex told Judge Burke that Dr. Buckton was talking about something else:

> *THE COURT: So you're saying, Mr. Jaros, that quote, I don't see any need to do any practical tests is* ***actually not*** *about tests regarding the, what we're calling the compounding process or the final manufacturing process for the accused product here.*
>
> *MR. JAROS: That's exactly right, Your Honor.*

[4] DRL, IMS, and Hospira's expert testified that it would only take a few weeks to perform tests of their own. *See* D.I. 870-7 (Steed Tr.) at 75:24-76:13.

Ex. 8 at 51:15-22 (emphasis added). The quoted testimony shows this is not "exactly right," Dr. Buckton was clearly saying he did not need to do any responsive testing.

III. SUMMARY OF THE ARGUMENT

Judge Burke clearly erred in striking the majority of Plaintiffs' infringement evidence developed during the supplemental discovery period. D.I. 874. Both bases for his decision are wrong.

1. Plaintiffs' infringement contentions and supplemental expert reports were not "untimely." Plaintiffs complied with Rule 26 and the supplemental discovery schedule. *See* D.I. 715 at 1-2, 717, 720 at 2, 796 at 2-3, 816 at 1. The Order below did not consider this.

2. Judge Burke's *Pennypack* analysis elevated Defendants' feigned surprise and prejudice towards the supplemental evidence over its criticality. That amounts to clear error. The supplemental evidence is premised on the same theory that has always been the heart of Plaintiffs' infringement case and Defendants identified nothing more they supposedly need to defend against it.

This Circuit favors resolving cases on their merits. That will not happen here if the Order stands. Indeed, the import of the Order is that Defendants get the benefit of changing their product in an attempt to strengthen their non-infringement defenses after seeing Plaintiffs' infringement proofs in full (Ex. 8 at 20:23-22:1), but Plaintiffs are stuck with the status quo.

IV. LEGAL STANDARDS

A district judge must modify or set aside any part of a timely-objected-to magistrate's order that is clearly erroneous or is contrary to law. Fed. R. Civ. P. 72(a); *see also* 28 U.S.C. § 636(b)(1)(A).

Rule 37 allows the Court to strike evidence not timely disclosed absent substantial justification. Fed. R. Civ. P. 37(c). Timely disclosed evidence is, of course, not subject to striking. *Id*. If the Court finds the evidence untimely, it assesses substantial justification under the *Pennypack* factors: (1) the surprise or prejudice to the moving party; (2) the ability of the moving party to cure any such prejudice; (3) the extent to which allowing the testimony would disrupt the order and efficiency of trial; (4) bad faith or willfulness in failing to comply; and (5) the importance of the testimony sought to be excluded. *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904–05 (3d Cir. 1977), *disavowed on other grounds*, *Goodman v. Lukens Steel Co.*, 777 F.2d 113 (3d Cir. 1985). Because "[t]he exclusion of critical evidence is an extreme sanction," it should be reserved for circumstances amounting to "willful deception or flagrant disregard of a court order by the proponent of the evidence." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791–92 (3d Cir. 1994) (internal quotation marks and citations omitted).

V. ARGUMENT

A. Plaintiffs' Infringement Theories Were Timely Disclosed

The testing contained in Plaintiffs' supplemental expert reports is consistent with the i[redacted] arguments contained in Plaintiffs' original Final Infringement Contentions served nearly a year ago. *See* D.I. 847-5. The Order's conclusion that portions of Plaintiff's supplemental contentions and expert reports are untimely ignored the fact that they ***were timely*** according to the supplemental discovery order. And it further overlooks that supplemental discovery was necessitated by Defendants' litigation-inspired DMF and ANDA amendments. For example, [redacted]

D.I. 847-2 at 4-7; *see also* D.I. 847-3 at 10. On these facts, the Order clearly errs in charging Plaintiffs' with advancing untimely disclosures.

B. Defendants Face No Surprise

The Order also errs in its finding that "Defendants were understandably surprised to see Plaintiffs' new theory asserted at what is truly the 11th hour." D.I. 874 at 4. There is no "new theory." As discussed above, Plaintiffs have ***always*** contended that [redacted]

[redacted] is not a sufficient difference to warrant a conclusion that Defendants were unfairly "surprised" under *Pennypack*. *Pennypack*, 559 F.2d at 904–05.

C. Defendants Face No Prejudice

Defendants have suffered no prejudice; they were afforded an opportunity to directly respond to—and did respond to—Plaintiffs' supplemental contentions and expert reports, thus curing any alleged prejudice. *See Bayer HealthCare LLC v. Baxalta Inc.*, No. 16-CV-1122-RGA, 2019 WL 297039, at *2–*3 (D. Del. Jan. 22, 2019); *Abbott Labs. v. Lupin Ltd.*, No. CIV.A. 09-152-LPS, 2011 WL 1897322, at *5 (D. Del. May 19, 2011).

The Order also speculates that Defendants were prejudiced for not having time to "investigate[] whether to perform additional (and lengthy) testing procedures in order to assess the accuracy of Plaintiffs' new theory" or "take additional discovery relevant to the theory." D.I. 874 at 4. But Defendants and their experts [redacted]. *See* D.I. 870-7 (Steed Tr.) at 74:10-76:13; 78:9-23. Indeed, Defendants' experts testified [redacted]. *See* D.I. 870 at 1; *see also* D.I. 870-5 (Buckton Tr.) at 72:13-17; *see also id.* at 71:21-22; *see also* D.I. 870-7 (Steed Tr.) at 74:12-14; *see also* D.I. 870-6 (Cockcroft Tr.) at 121:3-123:4. The Order is, therefore, clearly erroneous in finding prejudice where Defendants actually responded to the supplemental evidence and ***conceded*** there was nothing more they would have done.

D. Denial of Defendants' Motion Would Not Disrupt the Order or Efficiency of Trial

The Order's finding that "there is just not time to: (1) incorporate a new and significant infringement theory into the case; (2) allow Defendants to take relevant discovery; and (3) still keep the trial date" is similarly clearly erroneous. D.I. 874 at 4. The first two things have ***already been done***, so there is no need to change the trial date to accommodate any further discovery.

E. The Order Strikes Critical Evidence of Infringement

The Order's failure to substantively evaluate the importance of the portions of the contentions and expert reports that Defendants seek to exclude is clear error. The Order glosses over this *Pennypack* factor relying on the fact that Plaintiffs have ***other*** evidence of infringement. D.I. 874 at 4. However, by focusing on Plaintiffs' proofs of [redacted] that predate Defendants' amendments, the Order sidesteps *Pennypack*'s requirement of analyzing the importance of the supplemental evidence to Plaintiffs' case separate from the timing of such disclosures. In short, the evidence is "(newly) important" because the Defendants changed the ANDAs.

This analysis is crucial because "[c]ourts favor the resolution of disputes on their merits." *Abbott Labs*, 2011 WL 1897322, at *5 (*citing Prof'l Cleaning & Innovation Bldg. Servs., Inc., v. Kennedy Funding, Inc.*, 245 Fed. App'x 161, 165 (3d Cir. 2007)). Indeed, "exclusion of 'critical evidence,' such as an expert report on infringement, is an 'extreme sanction, not normally to be imposed absent a

showing of willful deception or flagrant disregard of a court order by the proponent of the evidence.'" *Id.* at *3 (*quoting Paoli*, 35 F.3d at 791–92). Here, the supplemental proofs [redacted] are critical to Plaintiffs' case because they directly respond to Defendants' DMF/ANDA amendments, which Defendants admit were made to strengthen their defenses. To deny Plaintiffs' direct response to Defendants' gamesmanship would deny Plaintiffs—and this Court—of critical evidence of infringement.

VI. CONCLUSION

Plaintiffs respectfully request that the Court sustain Plaintiffs' objections and deny Defendants' Motions to Strike (D.I. 824, 830).

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CERTIFICATE OF COMPLIANCE

This brief complies with the Standing Order and was prepared in a proportionally spaced, 14-point font and contains 2,498 words.

January 3, 2021

/s/ Robert M. Oakes
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